**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF INDIANA**
**INDIANAPOLIS DIVISION**

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| UNITED STATES and STATE OF INDIANA *ex rel.* JUDITH ROBINSON,<br><br>Plaintiffs/Relator,<br><br>v.<br><br>INDIANA UNIVERSITY HEALTH, INC. f/k/a CLARIAN HEALTH PARTNERS, INC., and HEALTHNET, INC.<br><br>Defendants. | Case No. 1:13-cv-2009-TWP-MJD<br><br>Judge Tanya Walton Pratt<br><br>Magistrate Judge Mark J. Dinsmore |

**DEFENDANT INDIANA UNIVERSITY HEALTH, INC.'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE SECOND AMENDED COMPLAINT**

Defendant Indiana University Health, Inc. f/k/a Clarian Health Partners, Inc. respectfully submits this reply memorandum of law in support of its motion to dismiss Counts I and II of Relator Judith Robinson's Second Amended Complaint, which allege that IU Health breached the federal False Claims Act and the Indiana False Claims Act by submitting claims for payment under the Indiana Medicaid program that violated the federal Anti-Kickback Statute.

## INTRODUCTION

Relator's opposition to IU Health's motion to dismiss confirms that her kickback-based claims should be dismissed for three independently sufficient reasons.[1] First, the complaint does not satisfy Fed. R. Civ. P. 9(b). Second, the complaint does not plausibly allege that any remuneration paid to Defendant HealthNet interfered with the medical judgment of HealthNet's doctors, such that it tainted those doctors' referrals. And, third, to the extent the alleged

[1] Unless otherwise defined, capitalized terms used in this brief (e.g., IU Health, FCA, AKS) have the same meaning as in IU Health's opening brief.

arrangements may otherwise implicate the AKS, three of the four arrangements are protected by a statutory exception on the face of the complaint.

Relator's opposition brief is notable for how much it does *not* dispute. With respect to Rule 9(b), for example, Relator does not dispute her failure to provide examples of specific claims that resulted from three of the four purported arrangements (the MFM, PACC, and Avondale agreements). And though she claims to have provided such examples for the fourth arrangement (the hospitalist agreement between IU Health and HealthNet), the complaint shows otherwise. None of the examples in the complaint is linked to the hospitalist arrangement.

Understandably, then, Relator's primary argument under Rule 9(b) is that claim-specific details simply are not required. In Relator's view, Rule 9(b) requires details about only the alleged kickback scheme, not the resulting claims. The case law, however—including all of the cases that Relator cites—uniformly rejects that proposition. Alleging liability under the False Claims Act requires providing details about actual *false claims*. Relator's failure to do so is fatal to her kickback theory.

Next, regarding whether Relator has adequately alleged improper referrals, Relator does not dispute that she must allege (and ultimately prove) that the remuneration IU Health allegedly paid to HealthNet had an undue influence on HealthNet doctors' referral decisions. She claims that the complaint meets this standard by alleging that HealthNet had "complete control" over where its doctors referred patients. But that grossly overstates the allegations. Conclusory generalities aside, the complaint at best suggests that IU Health at times expected to see increased referrals from HealthNet to Methodist Hospital. That innocuous fact does not plausibly suggest an AKS violation when the complaint says nothing about *how* HealthNet supposedly forced its doctors to refer patients to Methodist Hospital. And this omission is all the

more glaring when Relator is a former HealthNet doctor, has received discovery on these issues from both Defendants, and has made specific allegations about *other* policies imposed on HealthNet doctors. With nothing specific in the complaint to connect the dots between the alleged remuneration and the referrals that allegedly resulted, the kickback theory must be dismissed, regardless of Rule 9(b).

Finally, Relator does not dispute that, on the face of the complaint, three of the four alleged arrangements satisfy the three requirements set forth in the statutory exception for remuneration paid to an FQHC. *See* 42 U.S.C. § 1320a-7b(b)(3)(I). Her only argument against dismissal on this basis is that the statutory FQHC exception lacks independent force. In Relator's view, that exception instead must be applied through a regulatory safe harbor promulgated years later that also covers certain FQHC arrangements, but which has a different, nine-part test. *See* 42 C.F.R. § 1001.952(w). The government has filed a brief supporting Relator on this point (but not on any other issue). But neither Relator nor the government cite even a single case endorsing their view. Instead, the case law uniformly holds—and the statutory and regulatory text makes clear—that the AKS's statutory exceptions and regulatory safe harbors operate independently from one another. To suggest a different view, Relator and the government can cite only vague language from the FQHC exception's enacting legislation. But their position (unlike IU Health's) would nullify statutory language, break from the position taken elsewhere by the Department of Health and Human Services Office of Inspector General ("OIG"), and trample the preference against executive agencies using regulations to broaden the scope of a criminal statute (not to mention the rule of lenity). For this reason as well, IU Health's motion to dismiss should be granted.

## REPLY ARGUMENT

### I. RELATOR'S KICKBACK ALLEGATIONS DO NOT SATISFY RULE 9(B).

Relator does not dispute that, under Rule 9(b), she must allege her kickback theory with particularity. As IU Health explained (Filing No. 177 ("Opening Br.") at 9-11), Relator accordingly must "identify specific fraudulent transactions" for each alleged scheme. *United States ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.*, No. 1:10-cv-0526-JMS-TAB, 2012 WL 3949532, at *2 (S.D. Ind. Sept. 10, 2012); *see also United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 741-42 (7th Cir. 2007) (explaining that details are required "at an individualized transaction level"), *overruled on other grounds*, *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). Although the Rule 9(b) standard is flexible about *how* specific claims may be identified, there is no leeway on *whether* they may be identified. The Second Amended Complaint does not meet this standard for any (much less all) of the four alleged kickback schemes.

#### A. Rule 9(b) Requires Identifying Specific Claims, as Case After Case Has Held.

Relator does not argue that she has provided examples of claims for her four kickback schemes. Instead, she argues for a laxer view of Rule 9(b), under which the only necessary details "are those related to the *kickback scheme*, not the resulting claims submitted to the Government." Filing No. 193 ("Opp'n") at 6. That is simply incorrect.

Relator is seeking liability under the *False Claims* Act, not the Anti-Kickback Statute (which is not even privately enforceable). "False claim allegations must relate to actual money that was or might have been doled out by the government based upon actual and particularly-identified false representations." *United States ex rel. Gross v. Aids Research Alliance—Chicago*, 415 F.3d 601, 605 (7th Cir. 2005). This reflects that the alleged fraud is not the kickback scheme but the *resulting claims*, without which there can be no FCA liability. *See, e.g.*,

42 U.S.C. § 1320a-7b(g) (FCA liability requires a "claim that includes items or services resulting from" an AKS violation). Alleging details about only the scheme—without details on the actual claims—thus does not suffice to "state with particularity the circumstances *constituting fraud*." Fed. R. Civ. P. 9(b) (emphasis added); *see also, e.g.*, *United States ex rel. Lusby v. Rolls-Royce Corp.*, No. 1:03-CV-0680-SEB/WTL, 2007 WL 4557773, at *5 (S.D. Ind. Dec. 20, 2007) (explaining that, "because it is the claim for payment that is actionable under the Act," "[a]ctual claims must be specifically identified" in an FCA complaint). As *Lusby* explains, the need to identify specific claims is "well-established" with FCA claims. 2007 WL 4557773, at *5.

Relator responds that IU Health "mischaracterizes" the law. Opp'n at 5. But only Relator misreads the case law. She cites the *Schramm* decision, for example, to describe "a flexible approach" that does not require "a relator to produce the invoices (and accompanying representations) at the outset of the suit." Opp'n at 5 (quoting *U.S. ex rel. Schramm v. Fox Valley Physical Servs., S.C.*, No. 12 C 8262, 2015 WL 3862954, at *3 (N.D. Ill. June 22, 2015)). But the flexibility discussed in *Schramm* concerns *which*—not whether—claim-specific details are provided. Far from excusing such details (as Relator implies), the *Schramm* court *dismissed* a complaint for not providing "specificity as to *any particular claim*." 2015 WL 3862954, at *3. (emphasis added). The court explained that it "d[id] not expect relator to list *every* single patient, claim, or document involved, but [relator] must provide *at least some* representative examples." *Id.* (emphasis added) (quoting *Peterson v. Cmty. Gen. Hosp.*, No. 01 C 50356, 2003 WL 262515, at *2 (N.D. Ill. Feb. 7, 2003)).[2]

[2] After the *Schramm* relator then amended the complaint, the court denied a new motion to dismiss because the new pleading identified specific claims, by "list[ing] ten Medicare patients" whose treatment generated false claims and "includ[ing] the dates on which Schramm treated the patients and the codes she entered . . . for billing." *United States ex rel. Schramm v. Fox Valley Physical Servs., S.C.*, No. 12 C 8262, 2016 WL 537951, at *3-4 (N.D. Ill. Feb. 11, 2016). It was only because of these claim-specific details that the court held it unnecessary for relator to additionally "attach an actual claim submitted to Medicare or proof-of-payment received by defendants." *Id.* at *6; *see id.* at *7 (explaining how "Schramm *does* provide representative examples").

So too in the *Goldberg* case, which Relator cites as another example of Rule 9(b)'s "flexible nature." Opp'n at 4 (citing *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 821-22 (N.D. Ill. 2013)). The court there "appl[ied] Seventh Circuit precedent instructing that a complaint satisfies Rule 9(b) by providing the general outline of a fraudulent scheme *and detailed representative examples*." *Id.* at 821 (emphasis added). Although the complaint did not "fully detail all of the circumstances of the alleged" fraud, the *Goldberg* court held that the complaint satisfied Rule 9(b) in part by "*pleading specific representative examples*." *Id.* at 822 (emphasis added).

And in *Grubbs*—a case that Relator highlights despite it being from another circuit (Opp'n at 5)—the complaint alleged "*specific dates* that each doctor falsely claimed to have provided services to patients and often *the type of medical service or its [procedural] code* that would have been used in the bill." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) (emphasis added). Once again, the court afforded the relator flexibility only regarding *which* claim-specific details were provided—and found that "dates and descriptions of recorded, but unprovided, services" could sometimes be adequate, if the complaint's details yielded "a strong inference that those claims were submitted." *Id.* at 190-91.

Kickback theories are treated no differently. Trying to suggest otherwise, Relator cites *United States ex rel. Kroening v. Forest Pharm., Inc.*, No. 12-cv-366, 2016 WL 75066, at *6 (E.D. Wisc. Jan. 6, 2016). Opp'n at 6. But *Kroening* only echoes that "it is not the underlying fraudulent activity . . . but the *claim for payment* that is unlawful under the FCA." 2016 WL 75066, at *7 (emphasis added). Applying Rule 9(b), the *Kroening* court accordingly dismissed a complaint that "contain[ed] details of how the scheme worked"—including explicit details about the alleged kickbacks—because "there [was] no allegation of *any specific claim* being made."

*Id.* The court explained that "in only the barest sense does the amended complaint connect specific kickbacks to specific [claims]," as Rule 9(b) requires. *Id.* at *9. If Relator had the law right, *Kroening*—which she cites—would have come out the other way.

Indeed, there is no shortage of cases holding that a relator alleging FCA liability on the basis of purported kickbacks must allege not only the kickbacks but also the resulting claims with particularity. *See, e.g.*, *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 891 (5th Cir. 2013); *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 124 (W.D. Pa. 2006); *United States ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006); *United States ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *6 (E.D. Pa. June 3, 2015); *Hericks v. Lincare Inc.*, No. CIV.A. 07-387, 2014 WL 1225660, at *12 (E.D. Pa. Mar. 25, 2014); *St. John LaCorte v. Merck & Co.*, No. CIV.A. 99-3807, 2004 WL 1373276, at *1 (E.D. La. June 16, 2004). Far from being limited to "cases where circumstances which cause a claim to be false would be visible on the face of claims themselves" (Opp'n at 6), Rule 9(b)'s need for specifically identified false claims is imperative for *all* FCA cases, because the false claims are an essential component of the alleged fraud.

Some kickback cases have, to be sure, "focused only on the need for specifics regarding the kickbacks," as would be expected when those specifics are lacking. Opp'n at 7.[3] But these

[3] Relator contends that one of these cases, *United States ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F. Supp. 2d 872 (N.D. Ill. 2012), "expressly disagreed with the need for a specific claim to the Government." Opp'n at 8. But the *Grenadyor* court excused only the need for precise *invoices* because the relator had alleged *other* claim-specific details: "exact dates, exact amounts that he infers were billed to the government, exact copay amounts waived, exact customers, their exact medication, and the exact government program that was billed." 895 F. Supp. 2d at 880. (Relator also accuses IU Health of misrepresenting this case's subsequent history, because the Seventh Circuit affirmed a "later" Rule 9(b) dismissal. Opp'n at 8 n.2. But IU Health's opening brief stated not that the cited *Grenadyor* opinion was directly affirmed, but instead that the "*FCA claim dismissal* [was] affirmed." Opening Br. at 12 (emphasis added).)

cases do not (and could not) relax Rule 9(b)'s "well-established" need for claim-specific details on top of whatever other details comprise the underlying fraud. *Lusby*, 2007 WL 4557773, at *5.

**B. Relator Has Not Alleged Examples of Specific Claims Resulting from Any of the Four Alleged Kickback Arrangements.**

Relator spills much ink describing her four alleged kickback arrangements. *See* Opp'n at 9-18.[4] But these purported "details of how the scheme[s] worked" are not enough to satisfy Rule 9(b) with "no allegation of *any specific claim* being made" as a result of each scheme. *Kroening*, 2016 WL 75066, at *7 (emphasis added). And even Relator does not argue that she identifies specific claims for three of the four purported schemes: the MFM, PACC, and Avondale arrangements. *See* Opp'n at 13-18. Under the correct Rule 9(b) standard, then, there is no dispute that these three kickback theories should be dismissed.

For her fourth kickback scheme (the hospitalist arrangement), Relator claims that she has indeed provided "claims-level data," because "[e]very patient identified as a bad outcome or 'near miss' by Relator was referred by HealthNet to Methodist Hospital as a result of the Hospitalist Arrangement." Opp'n at 13 (citing Filing No. 162 ("Second Am. Compl.") ¶¶ 84(a)-(g), 87). But Relator does not *allege* this. The Second Amended Complaint makes no reference to the hospitalist arrangement when discussing these patients, all of whom were allegedly treated by certified nurse midwives ("CNMs"). *See* Second Am. Compl. ¶¶ 84, 87. And, crucially, the Second Amended Complaint never alleges with particularity that these patients were referred to Methodist Hospital instead of elsewhere *because of* the hospitalist arrangement. Thus, even if these patient details might satisfy Rule 9(b) for Relator's CNM theory of liability (for which the

[4] Relator also spends a page discussing "a 1999 Affiliation Agreement" between IU Health and HealthNet, but she never claims that this agreement itself violates the AKS or generated false claims. *See* Opp'n at 11 (stating merely that the Affiliation Agreement "paved the way" for the "four arrangements" at issue). Indeed, the Affiliation Agreement does not violate the AKS for several reasons.

missing referral details are irrelevant), they cannot save her kickback theory based on the hospitalist arrangement.

Similarly, the fact that "the majority of HealthNet patients are Medicaid recipients" is beside the point. Opp'n at 8. What matters for Relator's kickback theory is (1) whether these HealthNet patients were referred to Methodist Hospital, and (2) whether improper kickbacks caused such referrals. With no "representative examples of the alleged violations"—which must be not only "plausible" (*id.*) but alleged with *particularity*—the kickback theory cannot stand. *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 702 (N.D. Ill. 2012) (cited by Opp'n at 8).

**C. Relator's Notice Argument Does Not Help Her.**

Finally, Relator falls back on the point that "Defendants never once say that they do not understand the nature of the allegations raised against them, that they are inadequately equipped to respond to the charges levied by Relator, or that the detail of Relator's complaint leaves open the possibility that the charges of kickback violations are spurious or unfounded." Opp'n at 9. To be clear, Relator's kickback accusations *are* "spurious [and] unfounded." *Id.* Only through empty hand-waving improper under Rule 9(b) can Relator's complaint imply a nefarious kickback scheme. And Relator is dead wrong to suggest that Rule 9(b) is strictly about "Defendants' ability to understand or defend against the fraud alleged against them." Opp'n at 13.

"Rule 9(b) serves not only to give notice to defendants of the specific fraudulent conduct against which they must defend, but also to deter the filing of complaints as a pretext for the discovery of unknown wrongs, to protect [defendants] from the harm that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis." *Bly-Magee*

*v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001) (internal quotation marks omitted). The Seventh Circuit has made this clear repeatedly. *See, e.g.*, *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (Rule 9(b)'s "heightened pleading requirement is a response to the great harm to the reputation of a business firm or other enterprise a fraud claim can do"); *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 924 (7th Cir. 1992) ("Rule 9(b) ensures that a plaintiff have some basis for his accusations of fraud before making those accusations and thus discourages people from including such accusations in complaints simply to gain leverage for settlement or for other ulterior purposes."); *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999) (Rule 9(b) "assure[s] that the charge of fraud is responsible and supported, rather than defamatory and extortionate"); *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994) (Rule 9(b) serves "three main purposes: (1) protecting a defendant's reputation from harm; (2) minimizing 'strike suits' and 'fishing expeditions'; and (3) providing notice of the claim to the adverse party."). And the danger of "defamatory and extortionate" fraud accusations made for "ulterior purposes" rings especially true here, given Relator's eagerness to use inflammatory language in her papers. *Ackerman*, 172 F.3d at 469; *Uni*Quality*, 974 F.2d at 924; *see, e.g.*, Second Am. Compl. ¶ 4 (accusing Defendants of "profiting on newborns fighting for their lives" and "bilk[ing] taxpayers at any cost").

Thus, even if Relator's allegations adequately "gave notice" to IU Health about the alleged (and non-existent) fraud, Relator's failure to allege specific examples of claims that have purportedly resulted from the alleged kickback arrangements—even *after* Relator has received extensive discovery—requires her kickback theory to be dismissed under Rule 9(b).

## II. RELATOR HAS NOT ALLEGED ANY UNDUE INFLUENCE ON HEALTHNET DOCTORS' REFERRAL DECISIONS.

Relator also has not adequately alleged improper referrals, which are an essential component of any AKS violation. As IU Health has explained (Opening Br. at 15), because HealthNet does not *itself* refer patients, Relator's kickback theory requires that HealthNet (as the recipient of the alleged remuneration) have "unduly influence[d]" the referral decisions made by HealthNet doctors, so as to cloud or override these doctors' medical judgment. *United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004); *see also United States v. Patel*, 778 F.3d 607, 618 (7th Cir. 2015). Relator does not dispute any of this.[5]

Instead, Relator contends that she has satisfied this standard because of "the complete control HealthNet held over referrals from its clinics." Opp'n at 18. The complaint, however, does not remotely allege this.

Aside from an empty reference to "the weight of the allegations" (Opp'n at 19), Relator identifies four allegations that, in her view, establish the "complete control" essential to her kickback theory: (1) a statement from Don Trainor of HealthNet, in connection with the MFM arrangement, "that referrals would result from the proposed relationship between IU Health and HealthNet," (2) a proposal from IU Health that reflected "anticipated referrals" from the MFM clinic, (3) the "Frequently Asked Questions" section of HealthNet's website, and (4) a 2012 email from Mickki Ashworth, a HealthNet clinic manager. Opp'n at 19-20. But these scattershot allegations do not plausibly suggest any "undue influence" on HealthNet doctors.

First, Trainor's recognition "that referrals [to Methodist Hospital] would result" from establishing a HealthNet MFM clinic is a statement of the obvious, not some smoking gun.

[5] Instead, Relator argues that kickbacks need not be paid directly to physicians. Opp'n at 18-19. IU Health has never disagreed. *See* Opening Br. at 15.

Opp'n at 19. Because HealthNet's MFM clinic was located "on IU Health's campus" (Second Am. Compl. ¶ 56), patients there might naturally be referred to Methodist Hospital, which could be most convenient for them. But there is nothing inherently unlawful about an arrangement that *might* increase referrals. And, when deciding where to refer a patient, a doctor might be "influenced" (Opp'n at 20 n.7) by any number of factors, including where a hospital is located and the nature of the service needed. The key under the AKS—as Relator does not dispute—is whether the arrangement interferes with doctors' independent medical judgment. *See, e.g.*, *Patel*, 778 F.3d at 618; *Miles*, 360 F.3d at 480. Trainor's statement does not come close to suggesting such misconduct.

Moreover, even if an improper scheme might be *possible* in light of Trainor's statement, the allegations "stop[] short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Relator was *herself* a HealthNet doctor (who, further, has received discovery from Defendants on these issues), yet Relator does not allege with any specificity that HealthNet controlled or otherwise constrained where its doctors referred patients. If HealthNet really had done this, Relator surely would have alleged as much.

For similar reasons, Relator's kickback theory cannot rest on a preliminary budget that allegedly "valued the anticipated referrals" from a HealthNet MFM clinic. Opp'n at 20. Again, the question is not whether IU Health "anticipated" referrals but instead whether IU Health caused *improper* referrals by unduly influencing doctors' decisions. A budget spreadsheet implies nothing about *why* HealthNet doctors referred patients to Methodist Hospital, and certainly does not make it plausible that these doctors (who received no remuneration) were not exercising independent judgment.

The third allegation highlighted by Relator—the Frequently Asked Questions section of HealthNet's website—fares no better. Relator trumpets the website's statement that "[b]irths are attended by the HealthNet nurse-midwives at Methodist Hospital," which she sees as the tip of the iceberg for a massive kickback scheme. Opp'n at 20. But that is not a plausible spin on this innocuous public statement, particularly when Relator's theory requires "believ[ing] that [Defendants] knowingly and willfully were prepared to violate federal criminal law (and face all of the personal sanctions that might entail)." *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 677 (N.D. Ill. 2006).

So too with Ms. Ashworth's alleged statement in 2012 that "our patients deliver at Methodist." Opp'n at 20 (quoting Second Am. Compl. ¶ 46). That statement (for which the Second Amended Complaint provides no context) does not plausibly describe any "undue influence" on HealthNet doctors, as there is no information on *how* HealthNet would supposedly direct patients to Methodist Hospital. With no plausible link between the remuneration allegedly paid to HealthNet and the referrals allegedly made by HealthNet's doctors—and only conclusory allegations of undue influence—Relator's kickback theory should be dismissed.

## III. THERE IS NO DISPUTE THAT THREE OF THE ALLEGED SCHEMES SATISFY THE STATUTORY ELEMENTS OF THE FQHC EXCEPTION.

Finally, even if the four arrangements alleged by Relator implicate the AKS, three of them are protected by the AKS's statutory exception for certain remuneration paid to an FQHC. *See* 42 U.S.C. § 1320a-7b(b)(3)(I). As IU Health's opening brief explained, the MFM, PACC, and Avondale arrangements all satisfy the three requirements set forth in § 1320a-7b(b)(3)(I). Opening Br. at 17-18.

Relator does not disagree. Instead, Relator argues that these arrangements are protected from liability only if they *also* satisfy the nine-part test in the AKS's regulatory safe harbor for

certain FQHC arrangements. *See* 42 C.F.R. § 1001.952(w). In its Statement of Interest, the government has argued the same (while not taking a position on any of the parties' other arguments). *See* Filing No. 205. But neither Relator nor the government cites *any* case holding that the AKS's regulatory safe harbors, which are promulgated by the OIG, narrow the scope of the statutory exceptions.

To the contrary, the case law holds that the AKS's statutory exceptions and regulatory safe harbors "are *separate and independent* bases for which certain activities may be excluded from criminal liability under the anti-kickback statute." *United States v. Shaw*, 106 F. Supp. 2d 103, 113 (D. Mass. 2000); *see also United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006) (conduct may be protected by "a safe harbor *or* exception" (emphasis added)), *aff'd*, 517 F.3d 449 (7th Cir. 2008). Thus, "a defendant can avoid liability under the Anti-Kickback Statute by demonstrating that *either* a statutory *or* regulatory exception applies." *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 664 (W.D. Pa. 2014) (emphasis added). Indeed, an Illinois district court recently discussed the applicability of the statutory FQHC exception without ever mentioning the regulatory FQHC safe harbor. *See United States v. George*, No. 12-CR-559-7, 2016 WL 1161269, at *7 (N.D. Ill. Mar. 22, 2016).

The courts' consensus on this matter is no surprise. The regulatory safe harbors are authorized not by the statutory exceptions themselves, but instead by a provision that protects any *additional* "payment practice[s] specified by the Secretary in regulations pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 ["MPA"]." 42 U.S.C. § 1320a-7b(b)(3)(E). Similarly, when authorizing the regulatory safe harbors, § 14(a) of the MPA explicitly provides that they "shall be *in addition to*" the statutory exceptions codified directly within the AKS. Pub. L. 100-93, 101 Stat. 680 (emphasis added). To that end, the text

of the FQHC exception does not state or even suggest that it can be narrowed by regulation. *See* § 1320a-7b(b)(3)(I). And the FQHC safe harbor does not state or suggest that it limits the related exception. *See* 42 C.F.R. § 1001.952(w). Merging the safe harbor into the exception, as Relator seeks, would thus break with not only the case law but also the statutory and regulatory text.

Insisting otherwise, Relator and the government point to the legislation that enacted § 1320a-7b(b)(3)(I), which directed the Secretary of Health and Human Services to "establish, on an expedited basis, standards relating to the exception." Pub. L. 108-173, § 431(b), 117 Stat. 2287. But a call for "standards relating to the exception" cannot give the Secretary license to rewrite the statute through a safe harbor.

Instead, the safe harbor *expands* the scope of protected activity, by shielding conduct not already covered by the exception. The statutory exception's three-part test governs arrangements that *actually* "contribute[] to the ability of the [FQHC] to maintain or increase the availability, or enhance the quality, or services provided to a medically underserved population." § 1320a-7b(b)(3)(I). In contrast, the regulatory safe harbor's more demanding nine-part test covers arrangements that the FQHC "*reasonably expects* . . . to contribute meaningfully" to this goal. § 1001.952(w)(3) (emphasis added). The regulatory safe harbor is plainly "relat[ed] to the exception," 117 Stat. 2287, but there is no reason to think it supplants the exception. By arguing otherwise, Relator and the government effectively ask this Court to nullify § 1320a-7b(b)(3)(I).

Moreover, the government's position here departs from what the OIG has said in other contexts. Like the FQHC exception, the statutory exception for certain discounting practices has a related regulatory safe harbor. *See* § 1320a-7b(b)(3)(A) (discount exception); 42 C.F.R. § 1001.952(h) (discount safe harbor). When this safe harbor was proposed through notice-and-comment rulemaking, some parties were concerned that it could be read to "constrict the reach of

the statutory exception." 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999). But the OIG made clear that the safe harbor instead "enlarges upon the statutory exception," by "defining additional discounting practices not included in the statutory exception that are not abusive." *Id.* at 63528. Holding the opposite here with the FQHC exception and safe harbor would make a hash of the statutory and regulatory scheme. *See, e.g.*, 56 Fed. Reg. 35952, 35954 (July 29, 1991) (stating generally that the safe harbors "do[] not expand the scope of the activities that the statute prohibits").

Thus, contrary to Relator's and the government's suggestions, a *Chevron* analysis is immaterial. *See* Opp'n at 22 (discussing *Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984)); Filing No. 205 at 5 (same). IU Health is not claiming that the FQHC safe harbor is unreasonable, invalid, or otherwise ineffective. The only question is whether the regulation operates independently of the statutory exception, for which *Chevron* is irrelevant.

Finally, it bears emphasis that violating the AKS is a crime. By claiming the OIG can use regulations to narrow a statutory exception, Relator and the government are thus arguing that regulations can broaden the scope of a criminal statute. But "if Congress wants to assign the executive branch discretion to define criminal conduct, it must speak 'distinctly.'" *Carter v. Welles-Bowen Realty, Inc.*, 736 F.3d 722, 733 (6th Cir. 2013) (Sutton, J., concurring) (quoting *United States v. Grimaud*, 220 U.S. 506, 519 (1911)); *see also, e.g.*, *Abramski v. United States*, 134 S. Ct. 2259, 2274, (2014) ("[C]riminal laws are for courts, not for the Government, to construe."). And "the rule of lenity . . . requires doubts to be resolved against criminalizing conduct." *United States v. Bloom*, 149 F.3d 649, 656 (7th Cir. 1998). Thus, any ambiguity on the scope of the FQHC exception, or on the relationship between the exception and the safe

harbor, should be resolved in IU Health's favor—which further underscores the difficulties with Relator's position.

Relator responds that IU Health's position is problematic, because the FQHC exception—if not narrowed by the regulatory safe harbor—"would apply to virtually any arrangement involving" an FQHC. Opp'n at 22. Not so. The exception applies only to certain types of remuneration ("goods, items, services, donations, loans"), which must be provided pursuant to a formal "agreement," and which must "contribute[] to the ability of the [FQHC]" to serve "a medically underserved population." § 1320a-7b(b)(3)(I). Indeed, IU Health does not claim this exception protects the alleged hospitalist arrangement with HealthNet, because that arrangement—under which HealthNet is paid to provide staffing at Methodist Hospital—does not directly "contribute[]" to HealthNet's ability to serve "a medically underserved population." § 1320a-7b(b)(3)(I).

Rather, the hospitalist arrangement and the other three alleged arrangements as well are all protected by regulatory safe harbors (to the extent they implicate the AKS at all). Contrary to Relator's claim (Opp'n at 24), the only thing IU Health "concedes" is that these safe harbors do not apply on the face of the complaint. But because the FQHC statutory exception does apply to the MFM, PACC, and Avondale arrangements on the face of the complaint, her claims based on those purported kickback schemes should be dismissed.

## CONCLUSION

For the foregoing reasons, IU Health respectfully requests that the Court enter an order dismissing with prejudice all claims against IU Health and granting such further relief the Court deems necessary and appropriate.[6]

[6] In a footnote, Relator asks for leave to amend her complaint in the event this Court dismisses her kickback theory under Rule 9(b). Opp'n at 25 n.10. But this Court has already dismissed that theory once under

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Respectfully submitted,

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(continued…)

Rule 9(b), and Relator has attempted to replead with it with the benefit of discovery. Relator is not entitled to a third bite at the apple. *See, e.g.*, *Precision Cam, Inc. v. Fox & Fox*, No. 1:14-CV-00452-TWP, 2015 WL 803552, at *10 (S.D. Ind. Feb. 24, 2015) (Pratt, J.) (Seventh Circuit precedent "allow[s] for one opportunity to amend and that leave to amend may be properly denied for repeated failure to cure deficiencies by amendments previously allowed").

**CERTIFICATE OF SERVICE**

I certify that on July 22, 2016 a copy of the foregoing Defendant Indiana University Health, Inc.'s Reply Memorandum Of Law In Support Of Its Motion To Dismiss the Second Amended Complaint was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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